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510(K) SUMMARY

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a 510(k) Summary for TRELLIS™ Collagen Ribbon.

(a)(1). Submitted By:

Wright Medical Technology, Inc.
5677 Airline Road
Arlington, TN 38002

Date: OCT 07 2013

September 20, 2013

Contact Person:

Sarah Holtgrewe, RAC
Manager, Regulatory Affairs
Phone: (901) 867-4476
Fax: (901) 867-4190

(a)(2). Proprietary Name: TRELLIS™ Collagen Ribbon

Common Name: Animal-derived, surgical mesh

Classification Name and Reference: 21 CFR 878.3300 – Class II

Device Product Code, Device Panel: OWY: Mesh, Surgical, Collagen, Orthopedic, Reinforcement of Tendon

(a)(3). Predicate Device: K120019 - Collagen Ribbon

(a)(4). Device Description

The subject TRELLIS™ Collagen Ribbon is a narrow, ribbon-like collagen matrix which is identical in material and processing to the predicate WMT Collagen Ribbon (rebranded TRELLIS™ Collagen Ribbon – K120019) and includes the sizes of the predicate with an additional thickness offering. The ribbon-like dimensions of the subject device allow for the same surgical techniques as the predicate and the subject has the same intended use—reinforcement of soft tissue in orthopedic applications. The subject TRELLIS™ Collagen Ribbon is the identical source material to the predicate and is manufactured and sterilized in the same manner.

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(a)(5). Intended Use

The TRELLIS™ Collagen Ribbon is intended to reinforce soft tissue where weakness exists, specifically, for the reinforcement of soft tissue repaired by sutures or suture anchors during tendon repair surgery, including reinforcement of the rotator cuff, patellar, Achilles, biceps, quadriceps, peroneal, posterial tibial, and other tendons. The TRELLIS™ Collagen Ribbon is not intended to replace normal body structure or provide the full mechanical strength to support tendon repair. Sutures used to repair the tear and suture or bone anchors used to attach the tissue to the bone provide biomechanical strength for the tendon repair.

The indications for TRELLIS™ are the same as the legally marketed predicate device.

(a)(6). Technological Characteristics Comparison

The technological characteristics of the Collagen Ribbon Tissue Matrix are substantially equivalent to technological characteristics of the predicate identified in this 510(k) submission. The subject Collagen Ribbon is the identical source material to the predicate and is manufactured and sterilized in the same manner. The ribbon-like length and width dimensions of both the subject and predicate device allow for the same surgical techniques and intended use—reinforcement of soft tissue in orthopedic applications. The subject includes the thickness of the predicate and an additional thicker size offering.

(b)(1). Substantial Equivalence – Non-Clinical Evidence

An animal study was done to compare the cellular infiltration and revascularization characteristics of the subject 2.1 mm thick product to the predicate 1.3 mm thick product. Histology results indicated no difference in revascularization and cellular infiltration for the subject versus the predicate.

Rehydration, tensile, and suture retention testing of the subject material rehydrated in saline or blood shows acceptable performance characteristics and substantial equivalence to the predicate.

(b)(2). Substantial Equivalence – Clinical Evidence

N/A

(b)(3). Substantial Equivalence – Conclusions

The subject Collagen Ribbon is the identical source material to the predicate and is manufactured and sterilized in the same manner. Substantial equivalence of the thicker size option is confirmed through tensile and suture retention testing, rehydration testing, and animal histology data. The data and evidence presented in this Premarket Notification demonstrate that the subject device maintains the same minimum performance characteristics as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Wright Medical Technology, Incorporated
Ms. Sarah Holtgrewe
Manager, Regulatory Affairs
5677 Airline Road
Arlington, Tennessee 38002

October 7, 2013

Re: K131143
Trade/Device Name: TRELLIS™ Collagen Ribbon
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: OWY
Dated: September 13, 2013
Received: September 23, 2013

Dear Ms. Holtgrewe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K131143

Device Name
TRELLIS Collagen Ribbon

Indications for Use *(Describe)*
The TRELLIS Collagen Ribbon is intended to reinforce soft tissue where weakness exists, specifically, for the reinforcement of soft tissue repaired by sutures or suture anchors during tendon repair surgery, including reinforcement of the rotator cuff, patellar, Achilles, biceps, quadriceps, peroneal, posterial tibial, and other tendons. The TRELLIS Collagen Ribbon is not intended to replace normal body structure or provide the full mechanical strength to support tendon repair. Sutures used to repair the tear and suture or bone anchors used to attach the tissue to the bone provide biomechanical strength for the tendon repair.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Jiyoung Dang -S